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510(k) SUMMARY

OCT 5 2012

ABThera Open Abdomen Negative Pressure Therapy System

Date prepared	September 28, 2012
510(k) owner	KCI, Inc.
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)
Address	6203 Farinon Drive; San Antonio, Texas 78249
Fax number	210 255-6727
Name of contact person	Margaret Marsh
Name of the device	
Trade or proprietary name	ABThera Open Abdomen Negative Pressure Therapy System
Common or usual name	Negative pressure wound therapy system (comprised of a dressing, therapy unit and tubing set)
Classification name	Negative Pressure Wound Therapy Powered Suction Pump and Surgical Mesh Dressing
Legally marketed device(s) to which equivalence is claimed	The ABThera Open Abdomen Dressing cleared under K090489 and the ABThera Negative Pressure Therapy Unit cleared under K083357.
Device description	
Device design	The therapy system consists of a therapy unit which delivers negative pressure through a tubing set to the dressing which is placed into the open abdomen. Controls within the therapy unit monitor delivery of negative pressure and provide safety alarms. The dressing manifolds negative pressure from the therapy unit and protects abdominal contents. A canister collects wound fluids removed under negative pressure.
Intended use of the device	The ABThera Open Abdomen Negative Pressure Therapy System is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. The Intended Use of this system is in open abdominal wounds with exposed viscera including, but not limited to, abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating theater.

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Summary of the technological characteristics of the device compared to the predicate device	Dressing system	Same as predicate: Foam based dressing with occlusive drape
	Pressure sensing	Same as predicate: Via sensing pad in tubing line
	Therapy unit	Same as predicate: Pump for delivery of negative pressure wound therapy and removal of wound fluid with controls for monitoring of therapy parameters and provision of safety alarms
	Labeling	Labeling has been updated to provide new safety and use information.
Summary of tests conducted	The ABThera, V.A.C. ATS, InfoV.A.C. and V.A.C.Ulta Negative Pressure Therapy Units have all been evaluated in laboratory tests for use with the ABThera Open Abdomen Dressing. They have been confirmed to provide equivalent delivery of negative pressure and fluid removal when used in conjunction with the ABThera Open Abdominal Dressing.	
Conclusions drawn	Testing demonstrates that the above KCI Therapy Units are equivalently able to provide negative pressure therapy when used with the ABThera Open Abdomen Dressing. The labeling updates described in this submission inform the user of new safety information to help assure that the product is used as intended.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 5 2012

KCI USA, Incorporated (Kinetic Concepts, Incorporated)
% Ms. Margaret Marsh
Regulatory Affairs Technical Director
6203 Farinon Drive
San Antonio, Texas 78249

Re: K120499
Trade/Device Name: ABThera Open Abdomen Negative Pressure Therapy System
Regulation Number: 21 CFR 8780.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 28, 2012
Received: October 01, 2012

Dear Ms. Marsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): **K120499**

Device Name: ***ABThera Open Abdomen Negative Pressure Therapy System***

Indications for Use:

The ABThera Open Abdomen Negative Pressure Therapy System is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. The Intended Use of this system is in open abdominal wounds with exposed viscera including, but not limited to, abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating theater.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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